Standardizing Data Collection in Traumatic Brain Injury

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14. ABSTRACT

Collaboration among investigators, centers, countries and disciplines is essential to advancing the care for traumatic brain injury (TBI). It is then important that we ?speak the same language?. Great variability, however exists in data collection and coding of variables in TBI studies, confounding comparisons between and analysis across different studies. Randomized controlled trials can never address the many uncertainties around treatment approaches in TBI. Pooling data from different clinical studies and high-quality observational studies combined with Comparative Effectiveness Research may provide excellent alternatives in a cost-efficient way. Standardization of data collection and coding is essential to this purpose. Common Data Elements are presented for demographics and clinical variables applicable across the broad spectrum of TBI. Most recommendations represent a consensus, derived from clinical practice. Some recommendations concern novel approaches, for example towards assessing the intensity of therapy in severely injured patients. Up to three levels of detail for coding data elements were developed: basic, intermediate, and advanced, with the greatest level of detail in the advanced version. More detailed codings can be collapsed into the basic version. Templates were produced to summarize coding formats explanation of choices and recommendations for procedures. Endorsement of the recommendations has been obtained from many authoritative organisations. The development of Common Data Elements for TBI should be viewed as a continuing process: As more experience is gained, refinement and amendments will be required. This proposed process of standardization will facilitate Comparative Effectiveness Research and encourage high-quality meta-analysis of individual patient data.

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Abstract

Collaboration among investigators, centers, countries and disciplines is essential to advancing the care for traumatic brain injury (TBI). It is then important that we "speak the same language". Great variability, however, exists in data collection and coding of variables in TBI studies, confounding comparisons between and analysis across different studies. Randomized controlled trials can never address the many uncertainties around treatment approaches in TBI. Pooling data from different clinical studies and high-quality observational studies combined with Comparative Effectiveness Research may provide excellent alternatives in a cost-efficient way. Standardization of data collection and coding is essential to this purpose.

Common Data Elements are presented for demographics and clinical variables applicable across the broad spectrum of TBI. Most recommendations represent a consensus, derived from clinical practice. Some recommendations concern novel approaches, for example towards assessing the intensity of therapy in severely injured patients. Up to three levels of detail for coding data elements were developed: basic, intermediate, and advanced, with the greatest level of detail in the advanced version. More detailed codings can be collapsed into the basic version. Templates were produced to summarize coding formats, explanation of choices and recommendations for procedures. Endorsement of the recommendations has been obtained from many authoritative organisations. The development of Common Data Elements for TBI should be viewed as a continuing process: As more experience is gained, refinement and amendments will be required. This proposed process of standardization will

facilitate Comparative Effectiveness Research and encourage high-quality meta-analysis of individual patient data.

Key Words:

traumatic brain injury, common data elements, data collection, data coding, standardisation, clinical studies

Introduction

Traumatic brain injury (TBI) is a field in medicine with one of the greatest unmet needs (Maas et al., 2008). Globally, the incidence is increasing, mainly due to increasing traffic in low- and middle-income countries (Maas et al., 2008). In high-income countries, traffic legislation and improved car safety have resulted in a decrease in the incidence of TBI caused by road traffic incidents. Nevertheless, TBI remains a leading cause of death and disability in Europe and the US, both in children and young adults. There is therefore a great need to advance clinical care. In practice, however, much uncertainty exists about the benefits and risks of many treatment modalities, and the level of evidence underpinning authoritative guideline recommendations is relatively weak. These problems are aggravated by the heterogeneity of TBI in terms of cause, pathology, severity and prognosis. It would seem unlikely that we will ever be able to mount adequately powered trials to study all relevant treatment modalities.

Although Randomized Controlled Trials (RCTs) are considered the preferred approach for investigating novel therapies, these are costly and logistically demanding, and it is doubtful whether results obtained in selected populations of subjects enrolled into clinical trials in research centers are generalizable to the broader settings in which most of the care for TBI patients is provided. Pooling data from multiple studies (individual patient data analysis) and Comparative Effectiveness Research (CER) utilizing prospective observational data collection can provide alternative sources of evidence that can be

obtained in a more cost-efficient way. The direct relevance and potential of such approaches is illustrated by the results from the meta-analysis of individual patient data performed by the IMPACT study group and by the observation that major advances in clinical care for TBI have resulted from previous observational studies such as the US Traumatic Coma Databank (Foulkes et al., 1991), the European Brain Injury Consortium (EBIC) Core Data Survey (Murray et al., 1999), The Vietnam Head Injury Study (Salazar et al., 1995), and the Trauma Audit And Research Network Registry (TARN) (Patel et al., 2005). When undertaking high-quality observational data collection across multiple settings or when analyzing individual patient data from various studies, standardization of data collection and coding is essential. In TBI, there is no lack of data, but we can never take advantage of the potential resulting from the availability of these data if they have not been collected in a uniform way. A general consensus on choice and coding of variables (Common Data Elements) for TBI studies is not only highly desirable from a scientific point of view, but also from a perspective of cost efficiency because repeated development of case report forms for new studies will be obviated, and costs for funding agencies consequently reduced.

With these considerations in mind, an interagency workshop on standardization of data collection in TBI and Psychological Health was organized in March 2009 (Thurmond et al., 2010). General recommendations for collecting data on demographics and clinical assessment, neuroimaging studies, biomarkers and outcome for TBI have been published (Maas et al., 2010, Duhaime et al.,

2010, Manley et al., 2010, Wilde et al., 2010). Here we present the full scope of the recommendations for assessment and collection of clinical data in TBI trials and observational studies during the acute, subacute and chronic phases. The global aim is to develop TBI Common Data Elements for use across the broad spectrum of TBI. TBI was defined as: "An alteration in brain function, or other evidence of brain pathology, caused by an external cause" (Menon et al., 2010). The recommendations are presented in modular format in order to facilitate the production of common case report forms (CRF).

Methods

The process for developing Common Data Elements for TBI was consensus-driven. As multidisciplinary working group (WG), with representation from many agencies and organisations, we prepared preliminary recommendations for presentation during the interagency workshop on "Standardization of Data Collection in TBI and Psychological Health", which was held in March 2009, in Washington, D.C. The feedback obtained led to substantial refinements which were discussed during three subsequent face-to-face meetings, and implemented into a beta-version of the CDEs. This beta-version was discussed during a two-day meeting with international TBI experts from the fields of neurosurgery and intensive care medicine. Suggestions for further improvements were incorporated in subsequent releases. Templates were developed for each data element, providing information on definitions, coding formats, plausible values, recommendations for procedures and explanation of

choices. We sought to ensure compatibility with the NINDS-broad common data elements project (www.commondataelements.ninds.nih.gov).

Structure of CDEs

The proposed CDEs contain all essential data elements for use across the broad spectrum of TBI. Related elements were combined in modules, which are grouped together in categories. For example, the data elements "age, gender and race" are combined in the module "demographics" under the category "subject characteristics".

In total, eight main categories were identified:

- Participant/subject characteristics
- Participant and family history
- Injury/disease related events
- Assessments and examinations
- Treatments/interventions
- Protocol experience
- Adverse events and safety data
- Outcome and function

The overall structure of the CDEs is presented in Figure 1. We recognized that the required level of detail for coding elements may vary greatly according to the aim of a

particular study. We therefore present up to 3 possible levels for coding each element: basic, intermediate, and advanced. The greatest level of detail is provided in the advanced version. In every case, the more detailed formats can be collapsed into the intermediate or basic versions, thus facilitating analysis of individual patient data across studies. Figure 2 provides an example of these three levels of coding . Many of the recommended elements represent "plug-in" elements and can be used multiple times in the development of a CRF. For example, assessments of the Glasgow Coma Scale Score (GCS) and pupillary reactivity may be recorded prehospital, on admission, and repeatedly during the acute care phase.

The selection of CDEs, and the level of detail for their coding, will depend on specific study requirements. The proposed CDEs offer sufficient flexibility for broad application as basic, intermediate and advanced levels can be mixed when designing a CRF. An example of how data elements can be compiled for an acute care study on severe TBI is presented in Figure 3.

Description of clinical CDEs

A complete overview of the recommended clinical CDEs and their templates has been posted on the IMPACT website (www.tbi-impact.org). More general information will be additionally incorporated on the NINDS website (www.commondataelements.ninds.nih.gov). Below, we summarize a selection of the main recommendations differentiated per category.

Subject characteristics

The category *subject characteristics* contains modules on demographics (age, gender, race/ethnicity) and social status (including education, employment, marital status and living arrangements).

Age

Age can be recorded in years (for infants in weeks/months) or derived from the date of birth. We extensively discussed preferred choices. Concerns existed that date of birth might be considered a potential patient identifier or "protected health information" requiring adherence to Health Insurance Portabilty and Accountability Act (HIPAA) regulations in the US. Nevertheless, recording date of birth is recommended for intermediate and advanced versions because it is source-verifiable.

Recording age is considered essential to all TBI studies because causes of injury and consequences for patterns of damage vary by age. Age is also a strong predictor for outcome (Bullock et al., 2000, Mushkudiani et al., 2007).

Race and ethnicity

There are no international standards for classifying race and ethnicity. Recommendations for reporting race in at least five categories are mandated by the Office of Management and Budget (OMB) of the United States government (www.whitehouse.gov/OMB/FEDREG/OMBDIR15.html). We therefore took a pragmatic approach and chose to further subdivide the broad categories prescribed by the OMB at several levels. In subjects of multiracial origin, multiple categories may be marked.

Many reasons exist for recording race and ethnicity in TBI studies:

- to detect possible disparities in pre-injury health and access to health care in the acute and post-acute phases after TBI.
- To identify racial variations in drug pharmacokinetics or pharmacodynamics
- To clarify the demonstrated association between race and outcome, which is not related to differences in cause of injury or to injury severity (Mushkudiani et al., 2007).

Race and ethnicity are overlapping concepts, but given the constraints of the OMB recommendations, they should be documented separately. It should be recognized that race is perhaps more a social and cultural construct and that classification is not always anthropologically or scientifically based. Importantly, race should not be seen as a surrogate for genetic variation, as only approximately 10% of genetic variation occurs between races (Jorde and Wooding, 2004).

Education

We recommend recording both the number of years of education completed and the highest level achieved. Achievement is considered more relevant than attendance (number of years). Educational level is an important component of socioeconomic status, and the level of educational achievement is related to outcome in TBI.

Employment

Although return to work is often considered a relevant outcome parameter for subjects in the paid workforce, we should recognize that other social roles such as homemaker or volunteer worker are equally relevant. We therefore prefer the more general term "productive activity" and recommend collecting data on these role activities separately.

Participant and family history

The category "participant and family history" contains modules on medical history, history of TBI exposure, pre-existing medications, behavioral history, and family history. In contrast to many previous studies in which data on pre-existing conditions and pre-existing medications have been recorded in free text format, we strongly recommend the use of pre-specified formats. This is becoming increasingly relevant, as data from the European Union (https://webgate.ec.europa.eu/idb/documents/2009-IDB-Report_screen.pdf) and the Centers for Disease control in the USA (http://www.cdc.gov/traumaticbraininjury/tbi_ed.html) suggest that injuries in general, and traumatic brain injury in particular, are increasing in individuals over the age of 60, who may suffer from a broader range of pre-existing conditions and who may take a wide range of medications, including anticoagulant medication and platelet aggregation inhibitors.

Documentation of a history of previous TBI reflects the increasing understanding that repetitive injuries cause incremental damage and may be an important risk factor for neuropsychological sequelae, Alzheimer's disease and encephalopathy. For

documenting lifetime history of TBI, we recommend use of the Ohio State University TBI Identification Method Short Form (Corrigan et al., 2007)

Injury/disease related events

The category "injury/disease-related events" contains modules on presentation, injury severity, second insults and destination after initial evaluation.

Presentation

We recommend different formats for recording details on initial evaluation and referral for patients presenting early vs. those presenting late. For patients who present early, referral policy, mode of transport and emergency medical care, as well as time of arrival, are relevant. For patients presenting late after injury, the main reason for presentation is perhaps the more relevant factor, and this will facilitate later characterization of the population captured. Late presentation is particularly common in individuals with mild TBI. Military service members and athletes may tend to avoid seeking immediate care or to minimize symptoms in order to fulfil their mission/game objectives and to not let down their comrades/team. Moreover, these groups are prone to repetitive injuries. Once these patients are in more usual or less structured environments, symptoms that seemed manageable may not resolve and may lead injured individuals to seek care long after injury, or after repetitive exposures. Late presentations based on self-report present problems for clinicians required to diagnose these injuries long after the event, and to systems that seek to provide fair compensation to injured individuals. In such situations it can sometimes be very difficult to establish a diagnosis of mild TBI definitively.

Definitions of mild TBI vary considerably across studies (Comper et al 2005). The American Congress of Rehabilitation Medicine has presented criteria for mild TBI, defining a loss of consciousness (LOC) of less than 30 minutes and post-traumatic amnesia (PTA) of less than 24 hours (ACRM 1993). Alteration of consciousness (AOC) not involving LOC or PTA (i.e., being dazed or confused, or patients reports that they saw 'stars' at the time of injury) is also included as indicating a mild TBI. Documentation of the presence of LOC, duration of PTA, other AOC (including confusion) and careful clinical interview are considered the best means of consolidating clinical evaluations and self-report to provide diagnosis of TBI and to characterize its severity in these patients. For assessing complaints and symptoms in studies of conscious subjects captured immediately after injury, we advocate the use of the structured assessment as contained in the acute concussion evaluation forms.

Type of injury

Traditionally, TBI is divided into closed vs. penetrating injuries. We recommend a broader documentation of type of injury into four categories: closed, penetrating, blast and crush. This reflects the changing epidemiology and increased recognition of blast injuries of the brain as a specific entity (Wolf et al., 2009, Ling et al. 2009). Crush injuries result from a slow mechanical force applied to the skull, and are therefore different from acceleration/deceleration or impact trauma.

Place and cause of injury

Although nearly every TBI study conducted in the past has attempted to capture essential information on place and (external) cause of injury, approaches to coding have been inconsistent and often confuse different aspects For example, categories such as road traffic incident or fall may be lumped together with home, suicide or

work. We recommend a clearer separation in which place of injury captures information on the location (for example, street, home, work, sports field) and the element "cause of injury" being more directed towards a causative factor (e.g., road traffic incident or fall). We further advocate to record whether injuries were intentional or not.

Accurate documentation of cause and mechanism of injury is important for two reasons: first, the type of brain damage that may be expected varies by injury mechanism (e.g., more contusions in patients who have sustained a fall; potentially unique injury patterns associated with explosions/blasts)) and second, from a perspective of prevention. For more detailed recording of mechanisms of injury caused by road traffic incidents, we strongly recommend documenting the function of the victim and that of the "other party" separately. This is relevant because vulnerable road users (pedestrians, cyclists and motor cyclists) are particularly at risk and account for almost half of all deaths due to road traffic incidents (WHO/OMS, 2009). In keeping with the addition of blast as separate type of brain trauma (above), we also include explosions/blasts as a mechanism of injury that should be documented in detail.

Classification

We recommend a broad and multidimensional approach to classifying the severity of both brain injury and extracranial injuries. Few studies conducted in the past have paid attention to the assessment and influence of extracranial injuries. Extracranial injuries, however, occur frequently in combination with TBI and are associated with poorer outcome, increased pain, and increased medication, perhaps more so in patients with mild to moderate injuries (McMahon et al1999; Van Leeuwen et al., in

preparation). For assessment of the severity of extracranial injuries, we recommend the use of a simplified version of the Abbreviated Injury Scale (AIS; med. AftAoA 1990) and calculation of the injury severity score (ISS) (Baker et al., 1974). For TBI patients we further consider it important to document the coexistence and severity of spinal injuries separately.

Severity of brain damage is commonly assessed by measuring the depth and duration of loss of consciousness and/or duration of posttraumatic amnesia , and by quantifying the extent of structural damage through neuroimaging. Subjects with TBI are commonly grouped into three distinct categories according to the Glasgow Coma Scale (GCS) score: severe (GCS 3-8), moderate (GCS 9-12), or mild (GCS 13-15). Although we strongly support the continued use of the GCS as an indication of the severity of brain damage, we should recognize that the severity lies across a spectrum and that categorization into a limited number of categories leads to loss of valuable information. Greatly different patterns of injury and pathology may be seen on structural imaging in patients with similar grades of clinical severity assessed by the GCS (Saatman et al., 2008). A more comprehensive and multidimensional approach to classification of TBI is advocated, but realization of this goal will require further research. An alternative approach to expressing severity is by prognostic classification in which the baseline prognostic risk for early mortality or functional outcome assessed by the Glasgow Outcome Scale is calculated. Validated models developed on large patient samples are now available (MRC CRASH Trial Collaborators, 2008; Steyerberg et al., 2008). We advocate increased use of these models. Consequently, documentation of the core predictors (Table 1) utilized in these models is considered essential for all TBI studies.

Second insults

Second insults may be systemic or intracranial and can aggravate processes of secondary damage in a brain rendered vulnerable by the primary injury. Systemic insults (e.g., hypoxia, hypotension and hypo/hyperthermia) may occur prehospital, during transport and in-hospital. We recommend different formats for coding such insults in the prehospital situation vs. in-hospital. Because accurate measurements are not always possible in the prehospital situation, we recommended a broad categorization. In-hospital, however, more detailed values are available. In the advanced version we therefore recommend detailed recordings on depth and duration of lower values, for example by presenting the percentage of time over which pre-defined ranges of values occur over a given period.

Assessments and examinations

The category *assessments and examinations* contains modules on vital signs and other body measures (e.g., height, weight), neurologic assessment (GCS, loss of consciousness, post-traumatic amnesia, alteration of consciousness), genetics, biomarkers and lab tests, imaging and non-imaging diagnostic tools. As a minimum, we advocate recording of vital signs (e.g., blood pressure, heart rate, temperature and oxygen saturation) on admission and further on a daily basis during the acute phase of the study. In the ICU environment, recording blood pressure and intracranial pressure (ICP) on an hourly basis is recommended in order to permit determination of the cerebral perfusion pressure (CPP). In the analysis phase, we recommend that all hourly data are referenced to date and time of injury, since this represents the only fixed time event that is common to all patients. Consensus on procedures for zeroing

the ICP monitor is required and we suggest zero calibration to the level of the foramen of Monro. In instances where a ventriculostomy is in place, ICP measurements will clearly depend on whether the ventriculostomy is left open, or kept closed, and only opened for elevations in ICP above a threshold. There is no consensus on this topic, and, for now, we recommend that clear information is provided about clinical practice in the context of the study. Indeed, provision of such information may allow us to undertake a CER analysis that addresses which of these approaches is better. It should be recognized however, that ICP measurements obtained by ventricular fluid pressure monitoring during continuous cerebrospinal fluid drainage are likely to be inaccurate, underestimating the real ICP.

Treatments and Interventions

The category 'treatments and interventions' includes modules on study treatments (investigational treatments), emergency care, in-hospital treatment and rehabilitation/post-acute care.

Emergency Service Therapeutic Procedures

The contribution of early events and the importance of ultra-early management of acute TBI have only recently been acknowledged. Even small degrees of suboptimal early management may have profound effects on outcome by creating a 'ripple effect', exacerbating or accelerating underlying pathophysiologic processes. Recommended elements for data collection include management of airway, breathing, and circulation, as well as the necessity for emergency intra- or extracranial surgery.

In-hospital treatment

The module on 'in-hospital treatment' includes elements for *concomitant medication, intra- or extracranial surgery and therapy intensity level*. Recording concomitant medication is often viewed as a nightmare by research personnel, but is essential, especially in the context of clinical trials with investigational medication in order to capture drug interactions. In addition to documenting the generic names of the medications given, we recommend a broad categorisation in order to facilitate analysis.

In previous trials, details on surgery have generally been entered in a free text format. This has in many cases precluded any meaningful analysis. We therefore recommend the use of predefined categories. A proposal is presented, but we realise that this is may be controversial and will elicit debate. For example, we do not consider insertion of chest tubes, or the implantation of a ventricular catheter for the sole purpose of monitoring as a surgical procedure. Practical experience and a process of validation will ultimately need to dictate further refinements.

Interpretation of ICP is not possible without knowledge of the *intensity of therapy* directed at ICP/CPP control. Modern neurocritical care practices have substantially blunted our ability to use ICP as a surrogate marker for a range of pathophysiologic processes. It is possible to control ICP by intensifying ICP/CPP therapies until the system terminally decompensates. In this context, the intensity of ICP/CPP targeted therapy may be a more sensitive measure of the severity of pathophysiology and of the ability of a novel intervention to modify such pathophysiology. Therapy Intensity Level (TIL) has commonly been recorded on an hourly basis, but this is resource-intensive. Further, ICU practices have changed, with most high-grade interventions now being used in a continuous fashion. Given this context, we had doubts whether

hourly recording of TIL justifies the investment in time. We therefore propose a novel approach with the expectation that this will offer a transparent and useful approach, coupled with a lower burden of data capture than hourly recording. For the basic level, we propose a simple 5-category scale, which permits a global approach to summarize the overall intensity of therapy over the entire treatment period or on a daily basis (Table 2). At the intermediate level, use of specific treatment modalities are scored on a daily basis or more frequently if required (Table 3). In the advanced level, details of fluid balance (volume loading), and administered doses of hyperosmolar fluids and vasopressors are captured additionally. The intermediate and advanced levels permit calculation of a numerical summary score which is compatible with the TIL score proposed for use in pediatric TBI (Shore et al 2006) (Table 3). A great advantage of this method is that it allows a commonality of approach in pediatric and adult populations. While the approach is ready for piloting, we recommend formal validation before widespread use.

Rehabilitation and post acute care

Consistent methods for tracking service utilization following treatment or acute care discharge are lacking. Several major issues must be considered when developing CDEs for use in the rehabilitation setting. First, there can be multiple pathways of care prior to initiation of post-acute care. Second, disparities in access to post-acute care may influence the recovery process and confound outcome assessment in acute care studies. A major challenge in the post-acute care phase is posed by the highly variable time periods at which data are recorded, confounding comparability of studies and interpretation of their results. Thus, it is the recommendation of this WG to develop a standard procedure for documenting post-acute service utilization after TBI at predetermined, fixed time periods.

Approximately 20% of those hospitalized acutely have sequelae serious enough to require and benefit from inpatient rehabilitation, which can occur in a variety of settings. Patients who are not expected to benefit from an active inpatient rehabilitation programme, are discharged home, to an outpatient rehabilitation programme, nursing home or other long-term care facility. Both in- and outpatient rehabilitation programmes focus on a variety of therapies (e.g., physical therapy, occupational therapy, speech therapy) to assist individuals in addressing a wide range of newly acquired impairments and activity limitations that may be cognitive, behavioral or physical in nature, with a goal of achieving the highest level of independence possible. Insurance coverage and patient financial resources may affect length of rehabilitation. The variability in access to and intensity of post-acute care currently provided makes a strong case for exploring preferred approaches with comparative effectiveness research. Standardisation of data collection is fundamental to such studies.

Protocol experience

This category includes modules on screening, enrolment criteria, informed consent, randomisation, protocol compliance and study completion. Many of these are study-specific. The modules on screening and informed consent warrant special emphasis.

Screening

The importance and relevance of documenting the results of screening procedures have been severely underrecognized in TBI. We present formats to capture exposure to TBI in civilian and military settings and formats for use in randomized clinical trials.

In RCTs, as well as in prospective observational studies, documentation of patient eligibility screening and exclusions is essential in order to monitor for the possibility of inadvertent selection bias, as mandated by the CONSORT Statement (Schulz et al. 2010).

Informed consent

Accepted approaches to informed consent procedures in acutely mentally incapacitated patients such as in TBI and then frequently in an emergency situation vary considerably between and even within countries. The necessity for and validity of proxy consent in such emergency situations is subject to much controversial debate (Kompanje et al. 2005, Stocchetti et al. 2004). It has been argued that proxy consent cannot be considered a substitute for respect of the autonomy of individuals and concerns have been raised about the validity of a balanced decision making by proxy in emergency situations. Approaches taken must comply with national regulations and be accepted by the local IRB. We recognize the following main types of informed consent procedures:

Informed consent: consent given on basis of verbal or written information, either by patient of legal representative.

Proxy consent: consent given by someone else than the patient, e.g. a legal representative or relative of the patient.

Consent by an independent physician: consent by a physician not directly related to the researcher or the department of the researcher, with no conflict of interest by the research project.

Deferred consent: consent given after enrollment by patient (deferred patient consent) or proxy (deferred proxy consent).

Waiver of consent/ Exception from consent (EFIC): partially waived consent, or waiver or alteration of all elements of consent (e.g. no verbal and no written consent).
EFIC was introduced in the U.S. to allow emergency research in settings of a life threatening disorder. EFIC is subject to very strict rules and regulations, written in the Federal Register 21 CFR 50.24. These rules include that it must be reviewed by the FDA, and requires both community consultation and adequate public disclosure. Where possible, patient or proxy consent should be sought later, but is not considered mandatory (in case of death, or when no relatives can be found). In every case in which EFIC procedures are followed, concerted efforts for obtaining (deferred) consent should be documented.

Accurate documentation of informed consent procedures is mandatory for all clinical studies, also for those without study related interventions. Accurate documentation of informed consent procedures employed, the time of obtaining consent and where appropriate the time of subsequent written confirmation is highly relevant and can be motivated from a legal and moral perspective and is mandatory in order to comply with ethical regulations.

Adverse events and safety data

Adverse event and safety data reporting is already largely standardized under the influence of regulatory authorities and Institutional Review Boards. However, templates are given on the above referenced websites.

Outcome and Function

Information on mortality is important to determine whether death was related to the injury or to other factors, to determine risk factors for death, and to identify causes of death that could possibly be prevented. We recommend recording the underlying cause of death. When extended data recording is undertaken, we further propose the listing of the three main causes leading to death using International Classification of Diseases, 10th Revision (ICD-10) codes. We further recommend investigation of the comparability between causes of death as captured in acute care studies by investigators versus those captured by nosologists, the medical record coders, assigning ICD-9 or ICD-10 codes.

Recommendations on the selection of instruments for assessing outcome have been proposed by Wilde et al (2010). Considerable overlap is recognized with functional assessments to assess progress during the post-acute care phase; as such, we recommend, wherever possible to use the instruments recommended by Wilde et al to this purpose also. Relevant domains for the assessment of progress during rehabilitation are the resolution of symptoms, functional independence and assessments of neuropsychological function. No single measure however, exists to capture the progress of a patient during all phases of recovery after TBI. We advocate further research in development of a valid, global clinical assessment tool for use in TBI rehabilitation.

Much interest in the occurrence of symptoms suggestive of post-traumatic stress disorder (PTSD) has arisen from the recent military experience, but relatively little is known about this in civilian TBI (Kennedy et al 2007). We therefore recommend the routine administration of the PTSD Checklist –Civilian Version (PCL-C) in all patients following TBI.

Discussion

We successfully developed general consensus on the coding of clinical data elements for use across the broad spectrum of TBI. The data elements are presented in a format for use as "building blocks" in the development of case report forms for TBI studies. We hope that these recommendations for Common Data Elements will promote better comparisons between studies and facilitate meta-analysis of individual patient data across studies. Standardization of data elements is essential in order to facilitate systematic reviews of evidence and to implement prospective Comparative Effectiveness Research in the field of TBI.

The recommendations presented have resulted from a large interagency initiative towards "an integrated approach to research in psychological health and traumatic brain injury" (Thurmond et al., 2010). Within this initiative, four working groups on TBI addressed aspects of standardization concerning demographics and clinical assessment, biomarkers, neuro-imaging, and outcome. The proceedings of the workshop have been published (Maas et al. 2010, Duhaime et al., 2010, Manley et al. 2010, and Wilde et al., 2010). For detailed information on the recommendations on neuroimaging, biomarkers and outcome, we refer to these publications. The diversity and specific characteristics of the topics addressed by the working groups resulted in a different emphasis in these recommendations. For example, in the recommendations of the biomarkers and imaging groups, emphasis was placed on standardization of techniques and procedures, whilst in the outcomes group the main emphasis was on the selection of instruments. For demographics and clinical assessments we considered standardisation of coding of the variables the most important. The

selection of variables to be recorded in a given study will be determined by the specific nature and focus of that study.

An element that might be considered core for an acute phase study, for example, may be totally irrelevant for an epidemiological or rehabilitation study. We consequently concluded that, at present, there was no rational foundation for either an evidence-based or consensus-based recommendation for selection of clinical variables. We considered it more relevant to propose different levels of coding for consistent and compatible documentation of variables across the diversity of settings in TBI.

We consider the process of developing standardization of data collection in TBI studies of great importance and crucial to advancing the care for TBI patients in the future. The recommendations have been well-received in the field, and endorsements have been obtained from the AANS/CNS section on Neurotrauma and Critical Care, the International and National Neurotrauma Societies, and the European Brain Injury Consortium. We emphasize, however, that the process of standardization is (and will remain) an ongoing process. The current proposals for Common Data Elements represent a beta-version, which will require further refinement and validation in clinical practice. An ongoing observational study coordinated by Dr. Geoff Manley at UCSF is a first approach towards such validation. Following subsequent refinement, further validation in broader settings is advocated. We recognize that much additional work is required. First, the modules require translation into a web-based entry format with pull-down menus and automated data checks. Second, we recognize that approaches to analysis of parameters that are continuously monitored in the ICU setting, such as ICP, have not been addressed yet. Current approaches are often crude and widely diverging, using only momentary or summary measures. Here, we

see a great need for advanced information technology input and further research into the best approaches for analysis.

Standardizing data collection and coding formats in TBI may well constitute one of the most important steps forward in the field of clinical TBI research, paving the road for harvesting successful results in the near future.

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Conflict of Interest statement:

The authors declare no conflict of interest. The process for developing the recommendations for standardisation of data collection in TBI studies was supported by a supplemental grant from NIH-NINDS (NS 042691) with additional support from the National Institute on Disability and Rehabilitation Research, the Department of Veterans Affairs, the Defense and Veterans Brain Injury Center and the Defense Centers of Excellence.

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Table 1: Elements required for IMPACT and CRASH prognostic models

IMPACT			CRASH	
Core model	**Extended model**	**Lab model**	**Core model**	**CT model**
	Core model plus:	*Extended model plus:*		*Core model plus:*
Age	- Hypoxia	- Glucose	**Age**	- Petechial haemorrhages
Motor score	- Hypotension	- Haemoglobin	**GCS score**	- Obliteration of the third ventricle or basal cisterns
Pupil reactivity	- CT classification		**Pupil reactivity**	- Subarachnoid bleeding
	- Traumatic subarachnoid haemorrhage on CT		**Major extracranial injury**	- Midline shift
	- Epidural mass on CT			- Non-evacuated haematoma

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Table 2. Therapy intensity level – basic

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◯	**TIL 0:**
	No specific ICP directed therapy
◯	**TIL 1 – Basic ICU care:**
	Sedation for ventilator/endotracheal tube tolerance Volume/Vasoactives for non-CNS cause (e.g. sepsis, myocardial injury) Head-up positioning (ventilator bundle) 'Normcapnia' ($PaCO_2 \geq 40$ mmHg)
◯	**TIL 2 – Mild:**
	Higher levels of sedation Vasopressors/volume for CPP support Low dose osmotic therapy Mild hypocapnia ($PaCO_2$: 4.6 - 5.3 kPa; 35 – 40 mmHg) CSF drainage <120 ml/day (<5 ml/hr)
◯	**TIL 3 – Moderate:**
	Higher doses of osmotic therapy Moderate hypocapnia ($PaCO_2$: 4.0 - 4.5 kPa; 30 – 35 mmHg) Mild hypothermia (>35°C) CSF drainage ≥120 ml/day (≥5 ml/hr)
◯	**TIL 4 – Extreme:**
	Profound hypocapnia ($PaCO_2$: <30 mmHg) Temperature <35°C Metabolic suppression with IV anesthetics Surgery for refractory ICP (decompression/lobectomy)

Table 3. Therapy intensity level – intermediate

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Assessments of therapy intensity

			Assignment of scores	
			Score	Max Score
◯ No	◯ Yes	Head elevation for ICP control	1	
◯ No	◯ Yes	Nursed flat (180°) for CPP management	1	1
◯ No	◯ Yes	Sedation (low dose as required for mechanical ventilation)	1	
◯ No	◯ Yes	Higher dose sedation for ICP control (not aiming for burst suppression)	2	
◯ No	◯ Yes	Metabolic suppression for ICP control with high dose barbiturates or propofol	5	
◯ No	◯ Yes	Neuromuscular blockade (paralysis)	3	8
◯ No	◯ Yes	CSF drainage <120 ml/day (<5 ml/hour)	2	
◯ No	◯ Yes	CSF drainage ≥120 ml (≥5 ml/hour)	3	3
◯ No	◯ Yes	Fluid loading for maintenance of cerebral perfusion	1	
◯ No	◯ Yes	Vasopressor therapy required for management of cerebral perfusion	1	2
◯ No	◯ Yes	Mild hypocapnia for ICP control [$PaCO_2$ 4.6 – 5.3 kPa (35 - 40 mmHg)]	1	
◯ No	◯ Yes	Moderate hypocapnia for ICP control [$PaCO_2$ ≥4 kPa (30 mmHg)]	2	
◯ No	◯ Yes	Intensive hypocapnia for ICP control [$PaCO_2$ <4 kPa (30 mmHg)]	4	4
◯ No	◯ Yes	Hyperosmolar therapy with mannitol up to 2 g/kg/24 hours	2	
◯ No	◯ Yes	Hyperosmolar therapy with hypertonic saline up to 0.3 g/kg/24 hours	2	
◯ No	◯ Yes	Hyperosmolar therapy with mannitol >2 g/kg/24 hours	3	
◯ No	◯ Yes	Hyperosmolar therapy with hypertonic saline >0.3 g/kg/24 hours	3	6
◯ No	◯ Yes	Treatment of fever (temp.>38°C) or spontaneous temp. of 34.5°C	1	
◯ No	◯ Yes	Mild hypothermia for ICP control with a lower limit of 35°C	2	
◯ No	◯ Yes	Hypothermia below 35°C	5	5
◯ No	◯ Yes	Intracranial operation for progressive mass lesion, not scheduled on admission	4	
◯ No	◯ Yes	Decompressive craniectomy	5	9
		Total maximal score:		**38***

* Maximum score corresponds to maximum score of PED version (Shore et al. 2006)

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Table 1. Working group members

Name	Institute	Specific expertise	Affiliation
David Adelson	Phoenix Children's Neuroscience Institute, Phoenix, AZ	Neurosurgery Pediatric TBI	Congress of Neurological Surgeons
Tom Balkin	Walter Reed Army Institute of Research, Washington, DC	Neuropsychology Military TBI	DOD
Ross Bullock	University of Miami Miller School of Medicine, Miami, FL	Neurosurgery Clinical trials	Member of ABIC
Doortje Engel	University Hospital Heidelberg, Germany	Neurotrauma research	
Wayne Gordon	Mount Sinai School of Medicine, New York NY	Rehabilitation Neuropsychology	NIDRR
Cynthia Harrison-Felix	Craig Hospital, Englewood, CO	Rehabilitation/ databases TBI	NIDRR
Jean Langlois-Orman	US Army Institute of Surgical Research, Fort Sam Houston, TX	Epidemiology	DOD
Henry L. Lew	Defense and Veterans Brain Injury Center (DVBIC), and Department of PM&R, Virginia Commonwealth University (VCU), Richmond, VA	Rehabilitation/physiatry	DVBIC
Andrew Maas	University Hospital Antwerp, Belgium	Neurosurgery Clinical trials	Member of INTS/ EBIC
David Menon	University of Cambridge, UK	Neuro-intensive care	Member of EBIC
Claudia Robertson	Baylor College of Medicine, Houston, TX	Neuro-intensive care	
Karen Schwab	Defense and Veterans Brain Injury Center, Washington, DC	Mild TBI/military	DCoE, DVBIC
Nancy Temkin	University of Washington, Seattle, WA	Biostatistics clinical trials	NIDRR
Alex Valadka	Seton Brain and Spine Institute, Austin, TX	Neurosurgery Severe TBI	
Mieke Verfaellie	Boston VA Healthcare System and Boston University School of Medicine, Boston, MA	Neuropsychology/rehab	VA
Mark Wainwright	Northwestern University, Chicago, Ill	Neurology Pediatric TBI	
David Wright	Emory University School of Medicine, Atlanta GA	Emergency medicine Mild TBI	

ABIC: American Brain Injury Consortium; DCoE: Defense Centers of Excellence; DoD: Department of Defense; DVBIC: Defense and Veterans Brain Injury Center;

EBIC: European Brain Injury Consortium; NIDRR: National Institute on Disability and Rehabilitation Research; TBI: Traumatic Brain Injury; VA: Department of Veterans Affairs.

Legends of figures.

Fig 1:

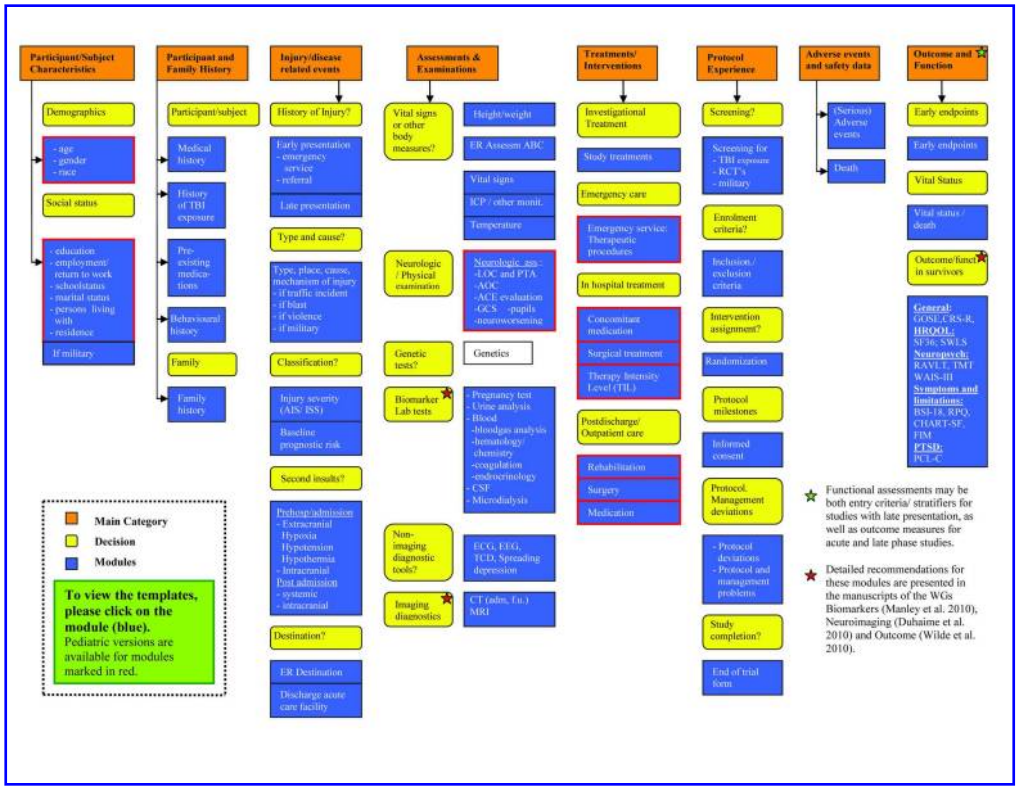
Structure of common data elements. Related elements are combined in modules (blue), which are grouped together in categories (orange).

Fig 2:

Example of the three levels for coding a data element, with the greatest level of detail in the advanced format.

Fig 3:

Example of how data elements can be used for designing a case report form for an acute care study on severe TBI.



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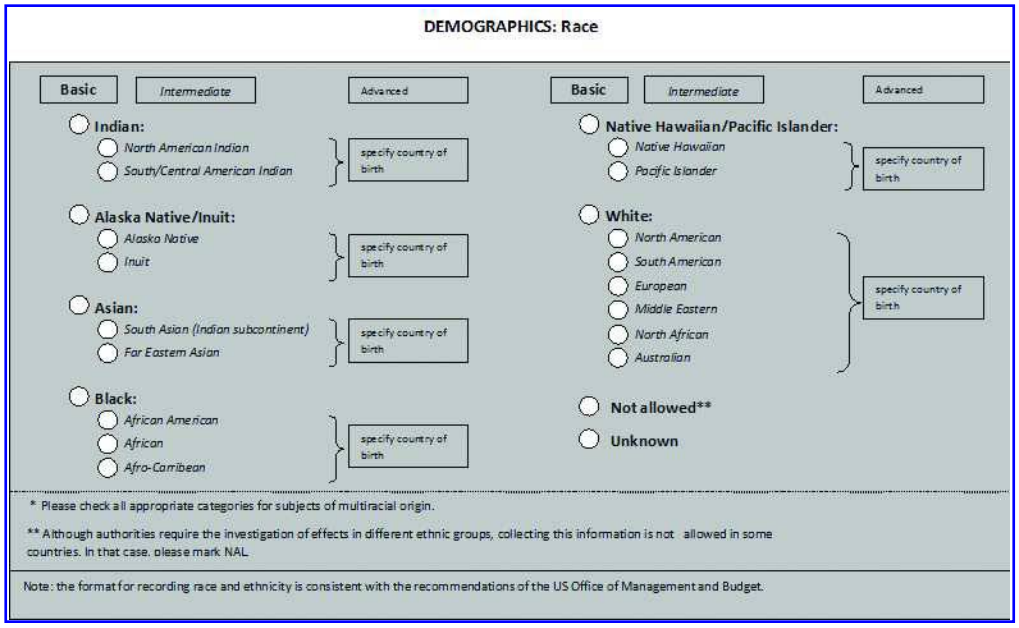

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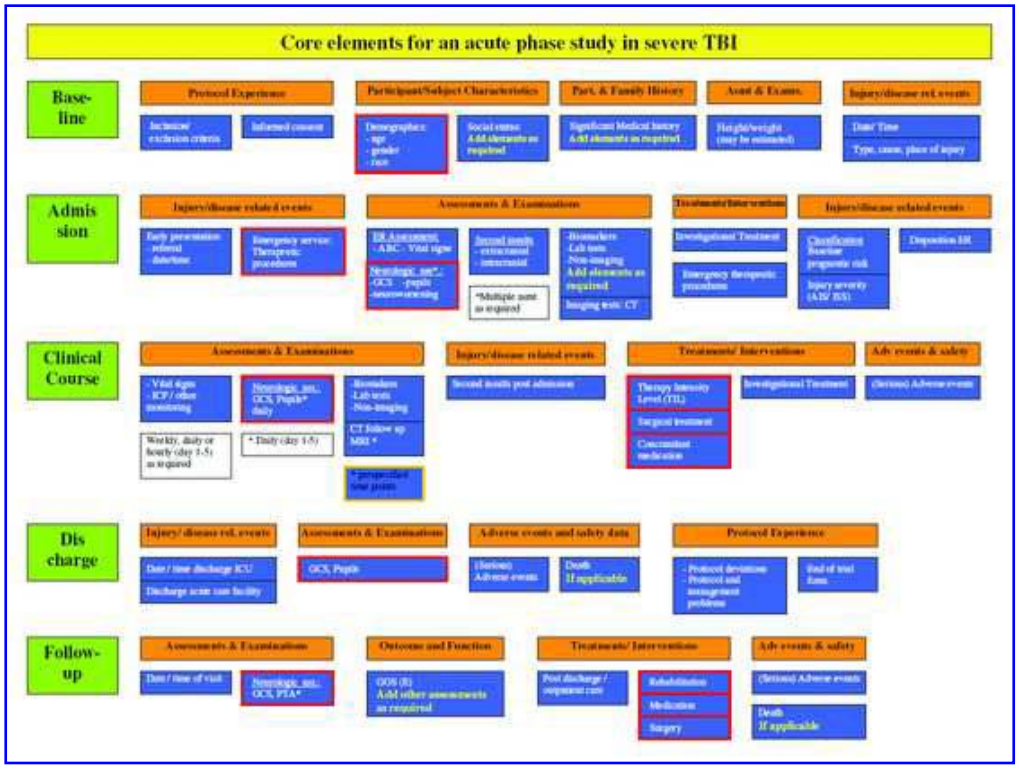

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